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IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

GILEAD SCIENCES, INC.,

Plaintiff and Counterdefendant,

v.

MERCK & CO., INC. (Defendant only), MERCK SHARP & DOHME CORP., and ISIS PHARMACEUTICALS, INC.

Defendants and Counterclaimants.

Case No. 5:13-cv-04057-BLF

DEFENDANTS' TRIAL BRIEF ON BENCH TRIAL ISSUES

Date: March 29, 2016
Time: 9.00 a.m.
Place: Courtroom 3 — 5th Floor
Before: The Honorable Beth Labson Freeman

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STATUTES AND RULES

Merck & Co., Inc., ("Merck & Co."), Merck Sharp & Dohm Corp. ("MSD Corp.") and Ionis Pharmaceuticals Inc., formerly known as Isis Pharmaceuticals, Inc. ("Ionis") (collectively, "Merck") respectfully submit this trial brief on Gilead's equitable defenses of unclean hands and waiver.

I. INTRODUCTION

Prior to the bench trial, Gilead will have lost on all the following issues:

(a) infringement- the Court has granted summary judgment that Gilead's sale of its Accused Products (Sovaldi® and Harvoni®) infringes each asserted claim of the Patents-in-Suit;

(b) liability- the jury found that all the asserted claims of the Patents-in-Suit are not proven invalid because the subject matter claimed is described and enabled by the patent applications that Merck filed on January 18, 2002; and

(c) damages–the jury will have determined the damages owed by Gilead for infringement from the launch of Sovaldi® up to December 31, 2015.

The equitable defenses (unclean hands and waiver) raised in this bench trial represent Gilead's last-ditch attempt to avoid the consequences of its adjudicated infringement of Merck's ten valid patent claims. Gilead's defenses are without merit and should be rejected by the Court.

Gilead's equitable defense of unclean hands is foreclosed by the jury verdict in this case. Gilead's unclean hands defense is based on the proposition that Merck "derived" the invention claimed in the Patents-in Suit from Pharmasset's confidential disclosure of a compound (PSI-6130) invented by Jeremy Clark. But the jury found that Merck's inventors were in possession of the claimed subject matter by January 18, 2002-well before Clark conceived the structure of PSI-6130 or even began working on HCV at Pharmasset. The jury's finding is binding in the subsequent bench trial and is fatal to Gilead's unclean hands defense. In any event, the uncontested evidence shows that Merck's pending claims covered the use of PSI-6130 as filed on January 18, 2002 and as amended in 2003 (before Pharmasset disclosed the structure of PSI-6130) and that Dr. Durette took no action concerning the '499 Patent until after Pharmasset had published the structure of PSI-6130, relieving him of any confidentiality obligations relating to that information.

Gilead's defense of waiver fares no better. The evidence shows that Merck did not engage in any conduct that manifested any decision that Merck would not assert its patent rights in the event the FDA

were to approve, and Pharmasset (or its successor, Gilead) were to launch, products containing sofosbuvir (also known as PSI-7977). On the contrary, the documented interactions between the parties show that Merck repeatedly warned Pharmasset that it needed a license under Merck's patent rights to commercialize sofosbuvir; that Pharmasset unsuccessfully sought such a license in 2010; that Pharmasset unsuccessfully attempted to find prior art to invalidate the '499 Patent; and when reminded that it needed a license under Merck's patent rights to sell sofosbuvir, Pharmasset responded that it hoped Merck's attorneys could "find the courthouse."

The evidence shows that Merck never waived its patent rights in favor of Pharmasset (or Gilead). Prior to Gilead's launch on December 6, 2013, Merck had no legal right to assert its patents against sofosbuvir, because Pharmasset and Gilead's pre-launch activities were protected by the FDA exemption codified at 35 U.S.C. § 271(e)(1). Merck expressly warned Pharmasset that it needed a license; offered Gilead a license on commercially reasonable terms (which Gilead spurned in favor of this declaratory judgment action), and asserted in its patent rights by way counterclaim once that legal remedy became available.

II. ARGUMENT

A. Gilead's Unclean Hands Defense Is Without Merit

1. The Binding Effect of the Jury Verdict

The Seventh Amendment to the U.S. Constitution provides:

> In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and *no fact tried by a jury, shall be otherwise reexamined in any court of the United States, than according to the rules of the common law*.

U.S. Const. amend. VII (emphasis added). Under the Seventh Amendment, a jury verdict rejecting Gilead's enablement and written description defenses for any asserted claims of the Patents-in-Suit will constrain the Court's equitable determination of any fact that is common to those legal defenses and the equitable defenses adjudicated in the bench trial.

Consistent with the requirements of *Dairy Queen, Inc. v. Wood*, 369 U.S. 469, 472-73 (1962), the Court properly held the jury trial on Gilead's legal defenses prior to the bench trial on Gilead's equitable defenses. To the extent the facts underlying the issues tried to the jury have "substantial commonality"

with the facts that underlie Gilead's equitable defenses, the Seventh Amendment constrains the Court's subsequent factual determination. *Cabinet Vision v. Cabnetware*, 129 F.3d 595, 600 (Fed. Cir. 1997); *see also Shum v. Intel, Corp.*, 499 F.3d 1272, 1279 (Fed. Cir. 2007) (while patent challenger would not have been entitled to a jury trial on its § 256 inventorship claim, standing alone, the presence of a fraud claim required the jury to determine facts that were common to the inventorship and fraud issues) (applying *Cabinet Vision*).

In particular, the jury's finding that each asserted claim was described and enabled by Merck's patent application filed on January 22, 2002 precludes any finding at the subsequent bench trial that the subject matter of that claim was *derived* from the *subsequent* invention by Jeremy Clark of PSI-1630 and its use to treat HCV infection. Since Gilead's theory of unclean hands depends on Merck's deriving its invention from Clark, the jury's verdict finding all of the asserted claims not invalid is fatal to Gilead's unclean hands defense.

2. Gilead's Unclean Hands Defense Is Precluded by the Jury Verdict in This Case

Gilead's defense of unclean hands is based on the contention that "Merck[] obtain[ed] its patent rights by deriving the invention from Pharmasset's confidential disclosures, which renders it inequitable for Merck to now assert the patents against Gilead, Pharmasset's successor-in-interest." Gilead's Supplemental Response to Interrogatory No. 12 (ECF No. 231-25 at 5-6).

Gilead's unclean hands defense is precluded by the jury's verdict in this case that each and every one of Merck's asserted claims was not invalid. The jury found that Gilead's evidence failed to prove that any of the asserted claims was (i) not enabled or (ii) not described by the applications that Merck filed on January 18, 2002. Since the jury found that Merck's inventors were in possession of the subject matter of the asserted claims on January 18, 2002, it follows that the claimed subject matter cannot have been derived from Pharmasset's **subsequent** disclosure to Merck of the **subsequent** work of Jeremy Clark, namely the compound PSI-6130 and its structure. These facts, found by the jury, are binding in the bench trial under Seventh Amendment principles.

The evidence shows that Jeremy Clark only began working on HCV no earlier than September 2002 (Deposition of Jeremy Clark; EX-2383.0002 at 21:02-08) and that Jeremy Clark only conceived of the structure of PSI-6130 in the fall of 2002 (Testimony of Michael Otto; Trial Tr. at 501:4-10). In view

of the jury's verdict, Gilead's unclean hands defense is insupportable.

3. The Legal Standard for Unclean Hands

Even if the jury's verdict did not preclude Gilead's unclean hands defense (which it does), it would still be fatally deficient. The doctrine of unclean hands arises from the maxim, "He who comes into equity must come with clean hands." *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 241 (1933). As applied to patents, this doctrine stems from three Supreme Court decisions, namely: (1) *Keystone*, (2) *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), *overruled on other grounds by Standard Oil Co. v. U.S.*, 429 U.S. 17 (1976), and (3) *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945). *See Therasense, Inc., v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285-87 (Fed. Cir. 2011) (en banc) (tracing the history and evolution of the unclean hands doctrine in patent law). In *Keystone*, the suitor in equity had manufactured and suppressed evidence. *Therasense*, 649 F.3d at 1285. *Hazel-Atlas* also involved the manufacture and suppression of evidence by the suitor in equity. *Therasense*, 649 F.3d at 1286. In *Precision*, suitor in equity suppressed evidence of perjury before the PTO and attempted to enforce the perjury-tainted patent. *Therasense*, 649 F.3d at 1286. Thus, each of these unclean hands cases dealt with "particularly egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence." *Id*. at 1287.

Unclean hands must be proved by clear and convincing evidence, *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1374 (Fed. Cir. 2007). The determination of unclean hands and the remedy, if found, are committed to the discretion of the trial court. *See Seller*, 621 F.3d at 986; *Aptix*, 269 F.3d at 1374.

The doctrine of inequitable conduct evolved from these unclean hands cases and came to embrace "a broader scope of misconduct, including not only egregious affirmative acts of misconduct intended to deceive both the PTO and the courts, but also the mere nondisclosure of information to the PTO. *Id*. Inequitable conduct requires clear and convincing evidence of both (i) the materiality of the wrongful act or omission to the patentability of the claims being sought, and (ii) a specific intent to deceive the PTO. *Id*. at 1290. Inequitable conduct "must be pled with particularity. *Exergen Corp., v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009); *Central Admixture Pharm. Servs., Inc. v. Adv. Cardiac Solutions, P.C.*, 482 F.3d 1347, 1356-57 (Fed. Cir. 2007). Gilead did not allege that Merck committed

inequitable conduct during the prosecution of the Patents-in Suit, and no such conduct occurred.

Though inequitable conduct developed from these unclean hands cases, "the unclean hands doctrine remains available to supply a remedy for *egregious misconduct like that in the Supreme Court cases*." *Id*. (emphasis added). Whereas inequitable conduct in prosecuting a patent may result in the patent being held unenforceable, a finding of unclean hands has more limited consequences. In *Keystone*, the Supreme Court affirmed a decision by the Sixth Circuit that directed the district court to dismiss Keystone's complaints "without prejudice." 290 U.S. at 244. The Court of Appeals was careful to prescribe the limits of its holding that the Supreme Court later affirmed: "The decrees of the District Court are reversed, and the causes are remanded, with instructions to dismiss the bills of complaint *without prejudice to the prosecution of suits at law*, or, indeed, to subsequent actions in equity upon the other patents in suit." *Gen. Excavator Co. v. Keystone Driller Co.*, 62 F.2d 48, 51 (6th Cir. 1932) (emphasis added). In cases where unclean hands arose from egregious misconduct in litigation, the Federal Circuit has affirmed dismissal of the action in which the misconduct occurred, but reversed the trial court's ruling that unclean hands rendered the patent unenforceable. *See Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1371, 1373 (Fed. Cir. 2001) (affirming dismissal of patent infringement action for unclean hands where the patentee had "submitted falsified engineering notebooks to the court" while emphasizing that the doctrine "does not reach out to extinguish a property right based on misconduct during litigation to enforce the right."). *Id*. at 1375; *accord Seller Agency v. Kennedy Center For Real Estate*, 621 F.3d 981, 987 (9th Cir. 2010) ("It is fundamental to [the] operation of the doctrine that the alleged misconduct of the [party] relate directly to the transaction concerning which the complaint is made.").

4. Gilead's Defense of Unclean Hands Is Not Supported by the Evidence

Even if the jury verdict did not foreclose this defense, it is unsupported by the evidence. Dr. Durette, the Merck attorney who prosecuted the '499 Patent, testified without contradiction that: (a) the claims in Merck's patent application generically covered PSI-6130 as filed in January 2002 (Trial Tr. at 388:13-19); (b) the preliminary amendment he filed on July 9, 2003 also covered PSI-6130 (*Id*. at 393:6-394:15); (c) after the 2004 phone call during which Pharmasset disclosed the structure of PSI-6130, he was aware that Merck's claims already covered that compound (*Id*. at 389:7-9); (d) the Clark application

that published in January 2005 disclosed PSI-6130 and together with data that showed this compound was "very active" (Id. at 389:14-390:14); (e) with the publication of the Clark application, Dr. Durette's obligations under the confidentiality agreement "terminated immediately" (*Id*. at 390:15-22).

In addition, there is no evidence connecting the above events with the prosecution of the '712 Patent. Gilead did not contend, and has submitted no evidence to show, that Jeffrey Bergman, the Merck attorney who took over prosecution of the '712 Patent many years after the 2004 due diligence call – from the attorney who *succeeded* Dr. Durette - was ever the recipient of the information that Pharmasset provided to Dr. Durette during that call. By the time that Mr. Bergman filed the claims that issued in the '712 Patent, Dr. Sofia at Pharmasset had published both the structure of PSI-7977 and the fact that PSI-7977 was a development compound in human clinical trials. EX-2214.

Gilead's unclean hands defense amounts to a complaint that Merck's attorneys prosecuted patent claims with the aim of covering products that Pharmasset was developing. The Federal Circuit long ago disposed of this canard: "there is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application." *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988). If "any such amendment [complies] with all statutes and regulations," as the jury's verdict will assure for the claims it upholds, "its genesis in the marketplace is simply irrelevant and cannot of itself evidence deceitful intent." *Id*.; *accord Ormco Corp. v. Align Technology, Inc.*, 647 F. Supp. 2d 1200, 1207 (C.D. Cal. 2009) ("that the patent owner knew of [the accused infringer's] processes and filed claims that covered these processes" did not support a finding of unclean hands) (applying *Kingsdown*); *Laitram Corp. v. Morehouse Indus., Inc.*, No S-94-0452, 1997 WL 33320572, at *13 (E.D. Cal. Apr. 24, 1997) (amendments "to cover competitors' products . . . are entirely appropriate so long as supported by the original disclosure.") (applying *Kingsdown*), *aff'd* 143 F.3d 1456 (Fed. Cir. 1998).

B. Gilead's Waiver Defense Is Without Merit

1. The Legal Standard for Waiver

Courts have recognized waiver as a cognizable defense to a charge of patent infringement.

Qualcomm Inc. v. Broadcom Corp, 548 F.3d 1004, 1019 (Fed. Cir. 2008). As applied to patents, two forms of waiver have been recognized: "true waiver" and "implied waiver."

True waiver requires a voluntary or intentional relinquishment of a known right. *Id*.; *accord Barnes & Noble, Inc. v. LSI Corp.*, 849 F. Supp. 2d. 925, 941 (N.D. Cal. 2012) ("A defense of waiver requires a showing of 'intentional relinquishment of a known right.'") (quoting *U.S. v. Perez*, 116 F.3d 840, 845 (9th Cir. 1997).

Courts have recognized a defense of implied waiver "in the context of standard-setting organizations" where "(1) the patentee had a duty of disclosure to the standard setting organization and (2) the patentee had breached that duty." *Id*. at 941-42 (citing *Hynix Semiconductor Inc. v. Rambus, Inc.*, 645 F.3d 1336, 1348 (Fed. Cir. 2011)); *accord Qualcomm Inc. v. Broadcom Corp.*, No. Civ. 05CV1958-B(BLM), 2007 WL 1031373, at *6-23 (S.D. Cal. Mar. 21, 2007) (finding implied waiver for breach of duty of disclosure to standard-setting organization), *aff'd* 548 F.3d at 1020-22.

Waiver must be proved by clear and convincing evidence. *Id*., 2007 WL 1031373 at *8-9.

2. Gilead's Defense of Waiver Is Not Supported by the Evidence

Gilead's defense of waiver (in common with Merck's now-abandoned defenses of laches and estoppel) is based on the contention that "Merck's assertion of patent rights in 2013 was unreasonably delayed; such delay was misleading conduct that led Pharmasset and Gilead to a reasonable belief that Merck did not consider PSI-6130 and/or PSI-7977 to be covered by its patents and pending applications; Pharmasset and Gilead relied upon this conduct; and Pharmasset and Gilead have now suffered material prejudice." Gilead's Supplemental Response to Interrogatory No. 11 (ECF No. 231-25 at 4-5). This defense is entirely meritless and is refuted by the evidence.

Gilead does not contend that Merck ever joined a standard-setting organization that imposed upon its members a duty to disclose or assert patents such as the Patents-in-Suit. Nor does Gilead identify a single affirmative statement by Merck that would support the remarkable conclusion that Merck voluntarily made a free gift to Pharmasset of the valuable patent rights that flowed from the painstaking work and brilliant insights of the Merck and Ionis inventors, achieved at great effort and expense. Gilead fails to explain any logical reason why Merck would give away its rights under the Patents-in-Suit without obtaining anything in return: no up-front licensing fees; no milestone payments; no running

royalties; not even compensation for the periodic maintenance fees that Merck paid to the PTO in order to maintain the patents (supposedly for Pharmasset's benefit).

The evidence tells a very different story. Pharmasset was on notice-long before the '499 Patent issued-that it did not have freedom to operate under Merck's patent applications that issued as the Patent-in-Suit.

As early as March 29, 2004 (over two years before the '499 Patent issued), Merck told Dr. Raymond Schinazi (Pharmasset's Executive Chairman) that Pharmasset did not have freedom to operate with regard to PSI-6130 in view of Merck's intellectual property. EX-2306. On August 10, 2004, Pharmasset acknowledged that "Merck has potential I.P. in the same space" that Pharmasset wished to operate, which would result in "a 50% reduction" from the price that Merck would pay to acquire Pharmasset. EX-1921.

On October 8, 2009, Pharmasset recognized that Merck would be "an ideal strategic partner" for its nucleotide program because "[c]onsolidating nucleos(t)ide IP would lower the legal risk of this program." EX-1770. Indeed, Pharmasset repeatedly tried to obtain a license under Merck's intellectual property rights. On May 25, 2010, Pharmasset asked Merck for a "[n]on-exclusive, worldwide license under Merck patent rights and know how to develop, manufacture and commercialize product containing Licensed Compounds [including PSI-7977]." EX-1634. When Merck's counter-proposal did not include such a license, Pharmasset asked again, on August 5, 2010, for a license and explained: "The licensing of Merck Patent Rights and Know-How is specific to the development, manufacture and commercialization of PSI-7977 as a Monotherapy Product, or as the PSI-7977 component of Pharmasset Combination Products." EX-1652 at 116:05-06.

In 2010, Merck executives warned P. Schaeffer Price (Pharmasset's CEO) that Pharmasset needed a license from Merck to commercialize PSI-7977. Mr. Price responded that he hoped that Merck's attorney could "find the courthouse." EX-2392.

As shown by the above evidence, Merck did not waive its patent rights in its discussions with Pharmasset, but on the contrary put Pharmasset on notice that Pharmasset did not have freedom to commercialize PSI-7977 (now sofosbuvir) without a license under Merck's patent estate.

Additional evidence shows that Pharmasset was well aware that Merck's patent rights presented

an obstacle to its plans for sofosbuvir. As recounted in a letter dated May 27, 2011 from Roche (Pharmasset's licensee and development partner), Pharmasset's outside IP counsel (David Maxwell) expressed the hope on September 8, 2010 that a then-pending arbitration would identify "disabling [prior] art against the Merck patent." EX-627. Mr. Maxwell acknowledged in December, 2010 that the arbitration decision "failed to provide the hoped for improvement of the prior art picture, at least against the U.S. patent within the '499 Series." *Id*. Such sentiments are entirely inconsistent with the proposition that Pharmasset considered that it had a royalty-free license under those Merck patent rights (whereas Pharmasset's competitors did not). In 2011, Roche took a license under the Patents-in-Suit at a royalty rate between 9-12%. EX-1783. As required under Roche's development agreement with Pharmasset, Roche sought Pharmasset's consent to the Roche-Merck license. EX-627. On or before September 7, 2011, Pharmasset consented to the Merck-Roche license. EX-2632. Pharmasset did not follow the same honorable course.

To the extent Gilead professes surprise that Merck did not earlier bring suit against the commercialization of sofosbuvir, the answer is simple: Merck did not have the legal right to do so. Gilead launched sofosbuvir in December 2013. EX-2374. Prior to that launch, Pharmasset and Gilead's pre-launch activities did not, as a matter of law, constitute infringement by virtue of the FDA exemption provided by 35 U.S.C. § 271(e)(1). *Merck KGaG v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 201 (2005) (§ 271(e)(1) provides an "exemption from infringement [that] extends to all uses of patented inventions that are reasonably related to the development and submission of any information under the [Federal Food, Drug, and Cosmetic Act] FDCA"); *Bio-Technology General Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1564 (Fed. Cir. 1996) ("With no legal right to enforce, it cannot be said that Genentech unreasonably delayed during that time period [before FDA approval and launch]."). The simple fact is that Merck had no cause of action that it could have asserted before Gilead commenced this declaratory judgment action on August 30, 2013.

III. CONCLUSION

For the above reasons, the Court should find that Gilead has failed to prove that waiver or unclean hands apply under the facts of this case.

Dated: March 22, 2016

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CERTIFICATE OF SERVICE

I certify that all counsel of record are being served on March 22, 2016 with a copy of this document via the Court's CM/ECF system.

/s/ Stephen S. Rabinowitz
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